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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,185	11/21/2003	Vladimir I. Slepnev	19781/2035	3232

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10/03/2006

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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,185

Applicant(s)

SLEPNEV, VLADIMIR I.

Examiner

Kenneth R. Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

1. The terminal disclaimer filed on 08/23/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/387,286 has been reviewed and is accepted. The terminal disclaimer has been recorded.

2. The specification is objected to because of the following informality: the continuation information must be updated to reflect the issue of the parent '286 application as US 7,081,339.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION BASED ON ART
SUPPLIED IN THE IDS OF 04/18/06**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11-14, 16, 22, 23, 25, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiesner (Nucleic Acids Res. 1992).

These claims are drawn to methods of quantitatively amplifying a plurality of nucleic acids, wherein an aliquot of the amplification mixture is dispensed or withdrawn at plural stages during the amplification regimen.

Wiesner teaches such methods; see entire document on pages 5863-5864.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-10, 15, 17-21, 24, and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesner in view of Schumm et al. (US 6,479,235).

These claims are drawn to methods as discussed and rejected above, further wherein at least three different amplification templates are used, or wherein capillary electrophoresis is utilized for separation.

The teachings of Wiesner are discussed above.

Wiesner does not disclose use of at least three different amplification templates, nor the use of capillary electrophoresis for nucleic acid separation.

Schumm et al. disclose the well-known technique of multiplex amplification wherein a plurality of different nucleic acid targets are simultaneously amplified, and that electrophoresis, preferably capillary electrophoresis, is used to separate the different products produced in multiplex amplification (see column 14, lines 52-64).

One of ordinary skill in the art would have been motivated to use a plurality of amplification targets, such as more than three, as well as the technique of capillary electrophoresis, in the method of Wiesner, because the advantages of both multiplex amplification and capillary electrophoresis were well known and common knowledge in the art, as demonstrated by Schumm et al. In other words, the skilled artisan considering these references would have been motivated to apply multiplex

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amplification and capillary electrophoresis as taught by Schumm et al. in the method of Wiesner to provide the obvious advantage of facilitating quantitative amplification profiles of large numbers of target nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

5. Claims 35-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesner in view of Brenner (US 6,228,589), and further in view of Schumm et al.

These claims are drawn to methods similar to those discussed and rejected above, wherein two amplification reactions corresponding to two gene expressing entities are carried out, and the resulting expression or transcription profiles are compared.

The teachings of Wiesner and Schumm et al. are discussed above.

Neither of these references teaches comparison of gene expression or transcription profiles from two different gene expressing entities.

Brenner discloses methods of measurement of gene expression profiles for use in toxicity screening, comprising comparing gene expression profiles from two different gene expressing entities (test vs. control organisms)(see column 5, line 66 to column 6, line 20).

One of ordinary skill in the art would have been motivated to carry out the method of Wiesner using two different gene expressing entities and comparing the resulting expression profiles, because as taught by Brenner such a comparison of gene

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expression profiles provides valuable information on the different states of the two entities, for example regarding toxicity after drug exposure. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

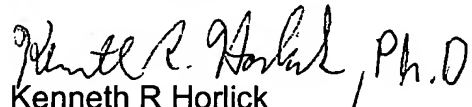
6. No claims are free of the prior art. It is noted that Wiesner et al. (BBRC 1992) and WO 98/33942 also teach a method wherein an aliquot of an amplification mixture is dispensed or withdrawn at plural stages during an amplification regimen.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kenneth R Horlick
Primary Examiner
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09/28/06